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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,072	01/02/2004	Sven Eyckerman	2676-6264US	2266

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,072	EYCKERMAN ET AL.	
	Examiner	Art Unit	
	Zachary C. Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,11,13,16 and 22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,11,13,16 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 4/25/06 has been entered.

Status of Application, Amendments and/or Claims

The amendment of 4/25/06 has been entered in full. Claims 1, 3-8, 11, 13, 16, and 22 are amended. Claims 9, 10, 12, 14 and 17-21 are canceled (claims 2, 15 and 23 were canceled previously).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-8, 11, 13, 16 and 22 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

The following page numbers refer to the previous Office Action (1/24/2006).

All rejections of claim 15 are moot in view of Applicants' cancellation of this claim.

The *provisional* double patenting rejection of claims 1, 3-8, 11, 13 and 22 over claims 1-5, 7, 12, 14 and 16 of copending Application No. 10/303157 in view of U.S. Patent No. 5,885,779 and in further view of Nicholson et al (2000) is withdrawn in view of Applicants' persuasive arguments at pg 5-6 of the 4/25/06 response.

Claim Rejections - 35 USC § 112, 2nd paragraph

Claims 1, 3-8, 11, 13, 16 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 22 are each indefinite because the metes and bounds of the term "recombinant mammalian receptor" are not clear. It is not clear whether only a single portion (such as the bait molecule) of the recombinant receptor needs to be mammalian in order for the receptor to meet the definition of "mammalian receptor", or whether all of the portions of the receptors (including the extracellular ligand-binding domain, the domain derived from cytoplasmic domain of a receptor, and the bait molecule) must be mammalian. For purposes of prosecution, the claims have been interpreted to broadly encompass either possibility.

Claim 16 is directed to a vector encoding a "recombinant mammalian receptor" and is therefore indefinite for the same reasons as claim 1.

The remaining claims are rejected for depending from an indefinite claim.

Claim Rejections - 35 USC § 102

Claims 1, 3-5, 11, 13, 16 and 22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Medici et al, 1997 (The EMBO Journal. 16(24): 7241-7249; cited previously).

Applicants' arguments (4/10/06; pg 6-8) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

Applicants argue (pg 7) that the claims as amended are limited to a recombinant mammalian receptor, and that Medici does not teach a mammalian receptor.

This argument has been fully considered but is not found to be persuasive. As noted in the section "Claim Rejections - 35 USC § 112, 2nd paragraph", the term "mammalian receptor" is indefinite and therefore has been broadly interpreted to encompass any receptor wherein a portion of the receptor is of mammalian origin. Medici teaches a chimeric receptor comprising any bait protein 'X' (Figure 6).

Furthermore, Medici specifically teaches a chimeric Ste2 receptor wherein the bait ('X') protein is the mammalian Raf oncoprotein (pg 7245). This Ste2-Raf receptor meets the definition of a 'mammalian receptor'.

Applicants further argue (pg 7-8) that amended claims 1 and 22 are directed to a receptor that comprises a cytoplasmic domain including at least one activation site, and that Medici does not teach a GPCR with an activation site on the cytoplasmic domain. Applicants argue that the person of ordinary skill in the art will understand that an activation site is limited to one or a few amino acids, and not a conformation change as taught by Medici. Applicants submit that according to the understood definition of an activation site, and as demonstrated by the examples in the specification, that modification of a conventional activation site refers to enzymatic modifications and does not include conformational changes that are not first induced by enzymatic modifications. Applicants further argue that the modifying enzyme activity must modify an activation site on the receptor chain, and Medici does not have any activation sites on the receptor cytoplasmic domain.

Applicants' arguments have been fully considered but are not found persuasive. The claims do not limit the activation site to constituting a "few amino acids". Nor does the specification provide such a limiting definition of an activation site (Applicants are invited to point the Examiner to such a definition in the specification). Further, Applicants do not provide any supporting evidence that the skilled artisan would recognize such a limited definition. Attorney arguments cannot substitute for evidence. The specification defines "activation site" (pg 14, ¶ [0059]) as "the site that, in the wild type receptor, is modified after binding of a ligand to the ligand binding domain, thus leading to a reorganization of the receptor and subsequent activation of the modifying enzyme activity and to which a compound of the signaling pathway can bind after modification, or any site that can fulfill a similar function." First, this definition indicates that the "activation site" is modified prior to activation of the "modifying enzyme activity", and therefore encompasses two independent forms of modification. Second, the definition does not limit the type of modification of the activation site, and therefore the definition encompasses any type of modification, e.g. phosphorylation or a conformation

change. Finally, it is noted that "modifying enzyme activity" is defined as "the enzymatic activity associated to or incorporated in the cytoplasmic domain of the receptor that is normally induced upon binding of the ligand to the ligand binding domain and subsequent reorganization of the receptor and may modify the activation site" (pg 14, ¶ [0060]).

The chimeric Ste2 receptors taught by Medici, including the Ste2-Raf receptor, have a site in the cytoplasmic domain that is encompassed by the definition of "activation site". Specifically, the Ste2 receptor has a cytoplasmic recognition site for the G-protein Gpa1 (see Figure 6, pg 7246 and the Discussion section from page 7246-7247). Ligand binding induces a conformation change that allows this recognition site to interact with the C-terminus of the G protein, and subsequent GDP/GTP exchange (which meets the definition of a "modifying enzyme activity" that is associated with a receptor). The limitation of "wherein the activation of said recombinant mammalian receptor is inhibited by binding of a fusion protein to said heterologous bait polypeptide" is an inherent characteristic of the receptor described by Medici. For example, any other fusion protein comprising Protein Y would inhibit (i.e., disrupt or reduce) the interaction between the GPCR-bait (Protein X) fusion protein and the G-protein-prey (Protein Y) fusion protein, resulting in inhibition of activation of the receptor (see Figure 6).

Applicants further dispute that the receptor taught by Medici would inherently be inhibited by binding of a fusion protein to the bait polypeptide. Applicants argue that "the assertion may only be true when both an active prey fusion protein and an inactive prey fusion protein are present" and that "in the Examiner's interpretation the receptor can only be activated by binding of another fusion protein", while the instant specification defines "inhibition of activation" as stating that the receptor is activated in the absence of binding.

Applicants' arguments have been fully considered but are not found to be persuasive. Applicants are reminded that the claims are directed to a product and not a method. The functional limitation that "activation of said recombinant receptor is inhibited by binding of a fusion protein to said heterologous bait polypeptide" merely limits the characteristics of the receptor that are found in the genus encompassed by

the claims. The receptor taught by Medici is activated by the binding of a prey molecule that comprises the chimeric G-protein; however, the same system would be inactivated by another molecule comprising a prey molecule and any other molecule (which would inherently be an inhibitor of activation). Therefore, the functional limitation presented in the claims does not distinguish the receptors encompassed by the claims from those taught by Medici.

Claim Rejections - 35 USC § 103

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medici et al, 1997 in view of Osborne et al, 1995 (cited by the Applicant in the IDS submitted 6/24/04).

Applicants' arguments (4/25/06; pg 8) as they pertain to the rejection have been fully considered but are not deemed to be persuasive for the following reasons.

Applicants' argue that Medici does not teach a recombinant mammalian receptor, and therefore Medici and Osborne, alone or in combination, fail to teach or suggest instant claims 6-8.

Applicants' arguments have been fully considered but are not found persuasive. As described above in the section entitled "Claim Rejections – 35 USC § 102", the receptor taught by Medici meets the limitation of "a recombinant mammalian receptor". Therefore, it is maintained that claims 6-8 remain unpatentable over Medici in view of Osborne as set forth at pg 7-8 in the 1/24/2006 Office Action.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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